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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,094	10/03/2006	Ramon Merce Vidal	284057US0PCT	9552
22850 7590 07/29/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER RICCI, CRAIG D	
			ART UNIT 4161	PAPER NUMBER
			NOTIFICATION DATE 07/29/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,094	Applicant(s) MERCE VIDAL ET AL.	
	Examiner CRAIG RICCI	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 20-45 and 48-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-19, and 46-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/07/2007, 4/21/2006, 4/17/2006, 1/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-73 are currently pending and the subject of this Office Action. Claims 15-17, 20-45, and 48-73 are withdrawn. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

2. All references have been considered.

Priority

3. The earliest effective filing date afforded the instantly claimed invention has been determined to be 07/29/2004 as to claims 1-14, 18-19, and 46-47.

4. Acknowledgment is made of Applicant's claim for foreign priority pursuant to 35 U.S.C. 119(a) and 365(b) based on a prior application filed in Spain on 7/30/2003. The certified copy has been filed in parent Application No. PCT/EP04/08511, filed on 07/29/2004.

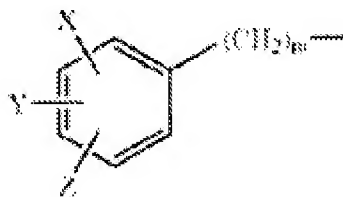
Election/Restrictions

5. Applicant's election with traverse of Group I, sulfonamide compounds in the reply filed on 5/21/2008 is acknowledged. Lack of unity was based on the fact that instant claim 14 includes the compound N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (claim 14, example 24) and furthermore *Mercede-Vidal et al* (WO 03/042175 A1) teach N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (Page 5, Lines 7-8, Example 1). Applicant argues that the teaching of *Mercede-Vidal et al* is incorrect and does not

correspond to the compound described in *Merce-Vidal et al.* Examiner disagrees. Rather, the instant application contains the misnamed compound and example 24 should read N-[1-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (compare instant examples 1 and 24). Applicant is advised to correct the instant application accordingly.

6. Examiner maintains unity of invention is broken based on *Merce-Vidal et al* as discussed below. The requirement is still deemed proper and is therefore made FINAL.

7. Applicant further elected the specie compound according to Formula (Ib) wherein

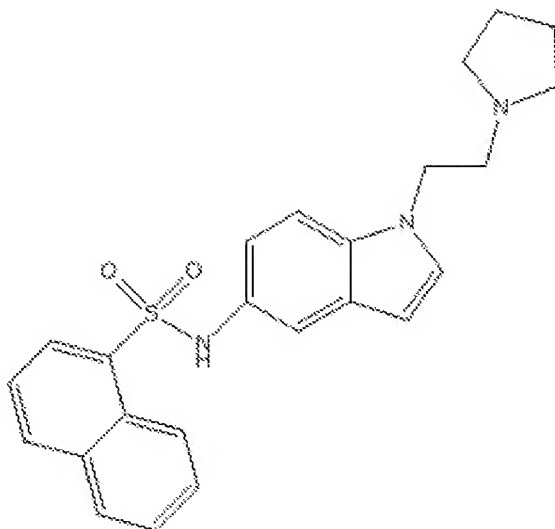


R1 is $(\text{CH}_3)_2\text{-N-}$; R2-7 is H; n is 2; and A is where m is 0 (zero); X is 2 nitro; Y and Z are H (i.e., A is 2 nitrophenyl). The elected species read upon claims 1-7, 9-14, 18-19 and 46-47.

8. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/21/2008.

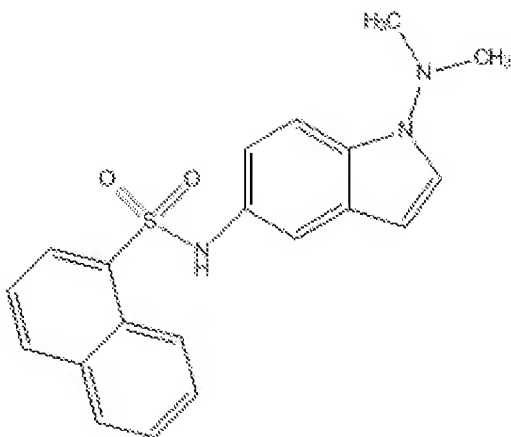
Allowable Subject Matter

9. The elected species was searched and is deemed free of the prior art. The search was therefor expanded as called for under Office Markush practice – a compound by compound search – to include a single additional species. That species



is defined as

(for claims 1-8 and 18-19)



and

(for claims 9-14 and 46-47).

10.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, for lacking antecedent basis.

13. Claim 14 recites the limitation " N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide" in claim 9. However, Formula (Ib) in claim 9 does not provide for the possibility of said compound. Accordingly, there is insufficient antecedent basis for this limitation in the claim.

14. Claims 1-7, 9-13, 18-19, and 46-47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

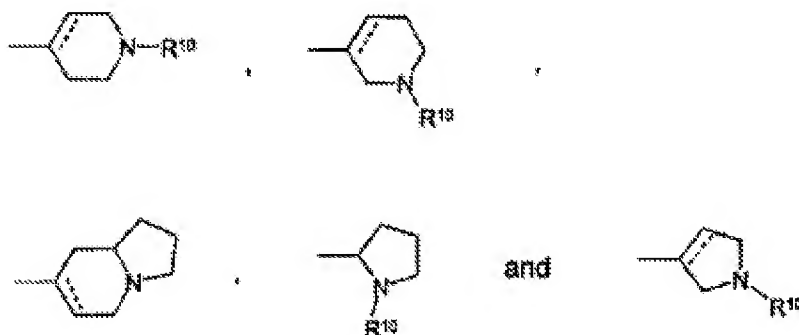
15. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 9, upon which claims 2-7, 10-13, 18-19, and 46-47 depend, recite the broad recitation "optionally

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in form of one of its stereoisomers” and the claim also recites “preferably enantiomers or diastereomers, its racemate or in form of a mixture of at least two of its stereoisomers, preferably enantiomers or diastereomers” which is the narrower statement of the range/limitation. Similarly, claim 2 states “at least one heteroatom as a ring member, whereby the rings of the ring system are 5- or 6-membered” (which is broad) and the narrower statement:

preferably R^1 represents an $-NR^2R^3$ radical or a radical chosen from the group consisting

of



Additionally, claims 3, 4, 7, 10, 11, 12, and 13 specifically contain broad recitations which are followed by narrower statements. Accordingly, claims 1-7, 9-13, 18-19, and 46-47 are rejected.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by *Merce-Vidal* (WO 03/042175 A1) for which *Merce-Vidal et al* (Canadian Patent Application CA 2466965) is being used as the English equivalent thereof.

17. Instant claim 14 is drawn to compounds according to claim 9 selected from the group consisting of N-[3-(2-diethylaminoethyl)-1H-indole-5-yl]-5-chloro-3-methylbenzo[b]thiophene-2-sulfonamide (instant claim 14, Example 24). *Merce Vidal et al* teach the instant compound (Page 4, Lines 30-31, Example 1). Accordingly, claim 14 is anticipated.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

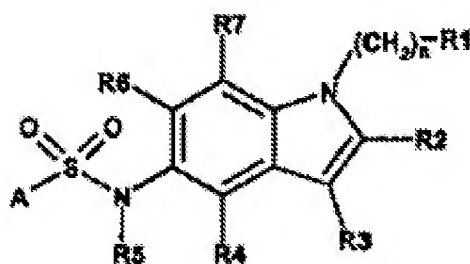
1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. **Claims 1-14, 18-19, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Merce-Vidal et al* (WO 03/042175 A1) in view of *Filla et al* (WO 02/060871) for which *Merce-Vidal et al* (Canadian Patent Application CA 2466965) is being used as the English equivalent thereof.**

22. Claim 1 teaches the following generic



compound

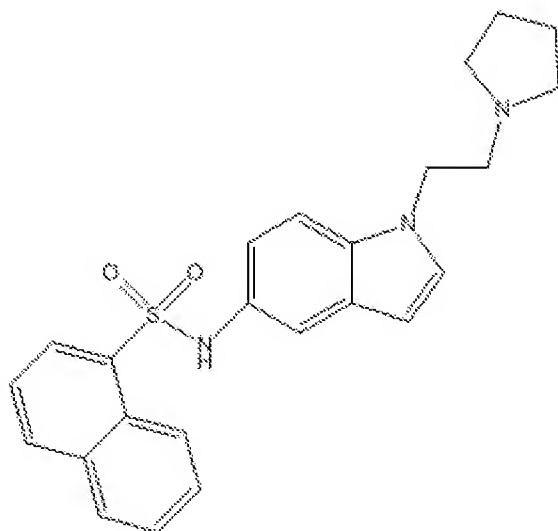
wherein the variable groups are

defined in the claim and which are compounds useful as 5-HT₆ modulators. More

specifically, claims 1-8 teach the specie of Formula (Ia) N-[1-(2-pyrrolidine-1-yl-ethyl)-

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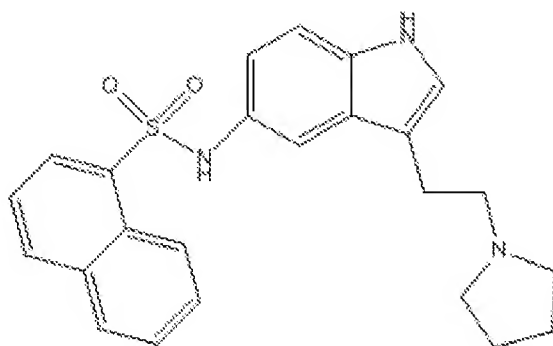
1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 8, Example 17) having the following



structure:

(Page 78, Example 17).

23. *Merce-Vidal et al* teach a 5-HT₆ modulator N-{3-[2-(pyrrolidin-1-yl)-ethyl]-1H-indole-5-yl}-naphthalene-1-sulfonamide (Page 6, Line 21, Example 45) having the



following structure:

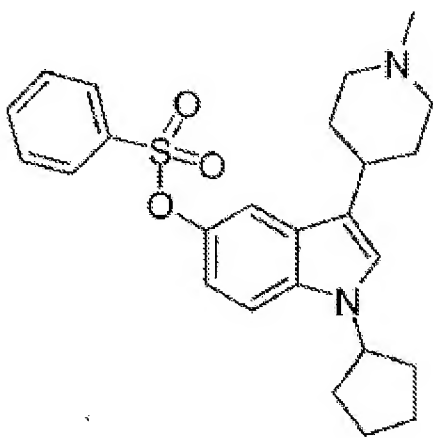
(Page 26, Example

45).

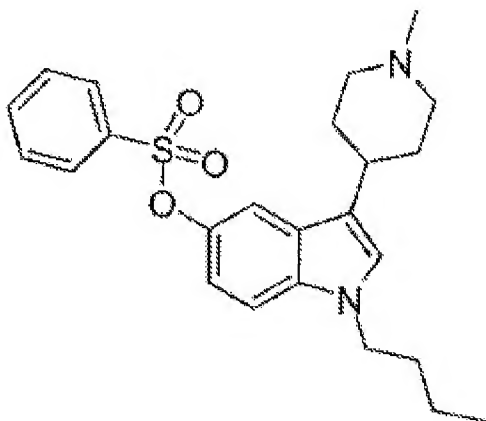
24. Accordingly, the only difference between the instant specie and that taught by *Merce-Vidal et al* is the placement of instant $-(CH_2)_n-R_1$ (wherein $-(CH_2)_n-R_1$ are the

same) on the indole core. The subtle differences that stem between the shift of $-(CH_2)_n-R_1$ from position 3 on the indole ring (as in *Merce-Vidal et al*) to position 1 on the indole ring (as in the instant application) are irrelevant since the MPEP 2144.09 states “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Moreover, *Filla et al* teach 5-HT₆ modulators such as the following compounds:

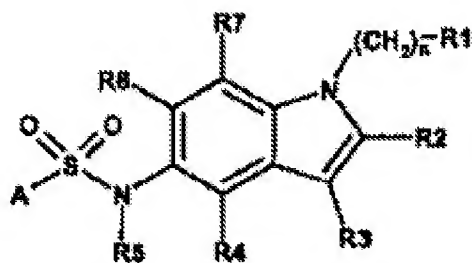


(Page 67, Example 28) and



(Page 68, Example 29) which teach substitution at position 1 on the indole ring. Thus, at the time the invention was made, one of ordinary skill in the art would have been motivated to take the $-(CH_2)_n-R_1$ group or similar variants, and place it at various positions on the indole ring (for example at position 1) to give 5-HT₆ modulators. Thus, the claims are obvious under 35 U.S.C. 103(a).

25. Claim 9 teaches the following generic

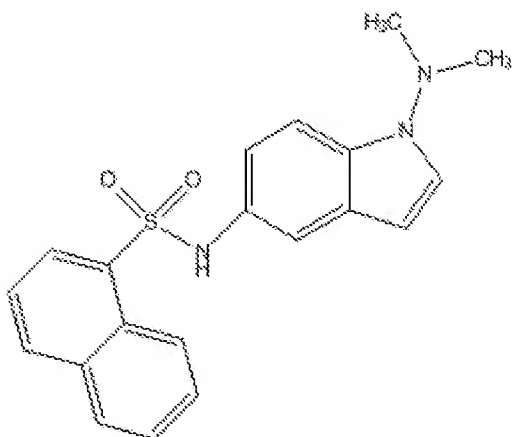


compound

wherein the variable groups are

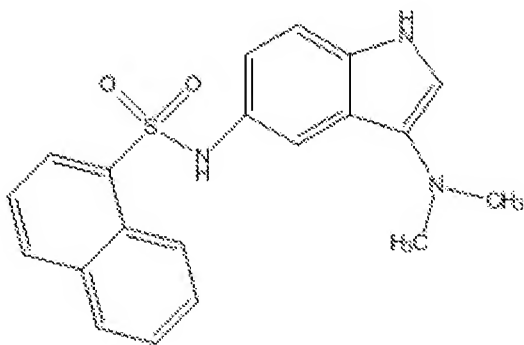
defined in the claim. More specifically, claims 9-14 teach the specie of Formula (Ib) N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14,

Example 3) having the following structure:



(Page 72, Example 3).

26. *Merce-Vidal et al* teach N-[3-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (Page 5, Line 3, Example 8) having the following structure:



(Page 16, Example 8).

27. Accordingly, the only difference between the instant specie and that taught by *Merce-Vidal et al* is the placement of instant $-(CH_2)_n-R_1$ (wherein $-(CH_2)_n-R_1$ are the same) on the indole core. The subtle differences that stem between the shift of $-(CH_2)_n-R_1$ from position 3 on the indole ring (as in *Merce-Vidal et al*) to position 1 on the indole ring (as in the instant application) are irrelevant since the MPEP 2144.09 states “Compounds which are position isomers (compounds having the same radicals in

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physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

28. Furthermore, as discussed above, *Filla et al* teach 5-HT₆ modulators containing the same instant core substituted at position 1 of the indole ring. Accordingly, one of ordinary skill in the art would have been motivated to take the -(CH₂)_n-R₁ group or similar variants, and place it at various positions on the indole ring (for example at position 1) to give 5-HT₆ modulators. Thus, the claims are obvious under 35 U.S.C. 103(a).

29. Claims 18 and 46 and drawn to medicaments including the compound of claim 1 or claim 9, respectively, an optionally at least one or more pharmacologically acceptable excipients. *Merce-Vidal et al* specifically teach “pharmaceutical compositions that comprise... an acceptable pharmaceutical excipient” (Page 11, Lines 6-8).

30. Claims 19 and 47 are drawn to the medicaments of claims 18 and 46, respectively, for the treatment of various conditions including, for example, anxiety. *Merce-Vidal et al* specifically teach “a medicament... useful for preventing or treating various disorders of the Central Nervous System, and particularly anxiety” (Page 11, Lines 11-12).

Double Patenting

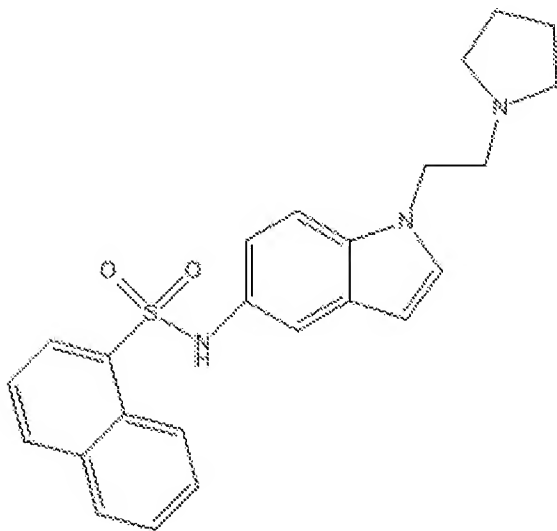
31. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

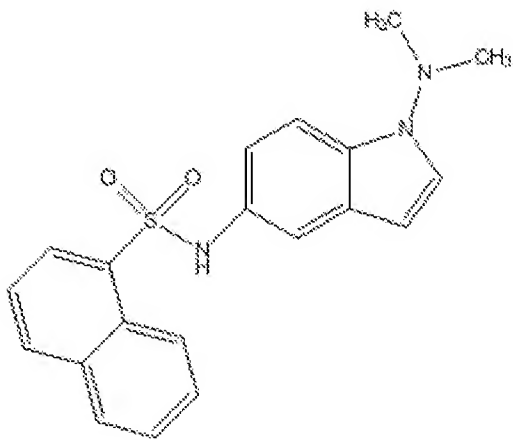
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

32. **Claims 1-14 and 18 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 46 of copending Application No. 10/566,101 in view of *Laconde et al* (J Enzyme Inhib Med Chem 18(2):89-94, 2003).** Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

33. As discussed above, the instant application teaches the specie of Formula (Ia) N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 8, Example 17) having the following structure:



(Page 78, Example 17) which encompasses claims 1-8 and Formula (Ib) N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 3) having the following structure:



(Page 72, Example 3) which encompasses

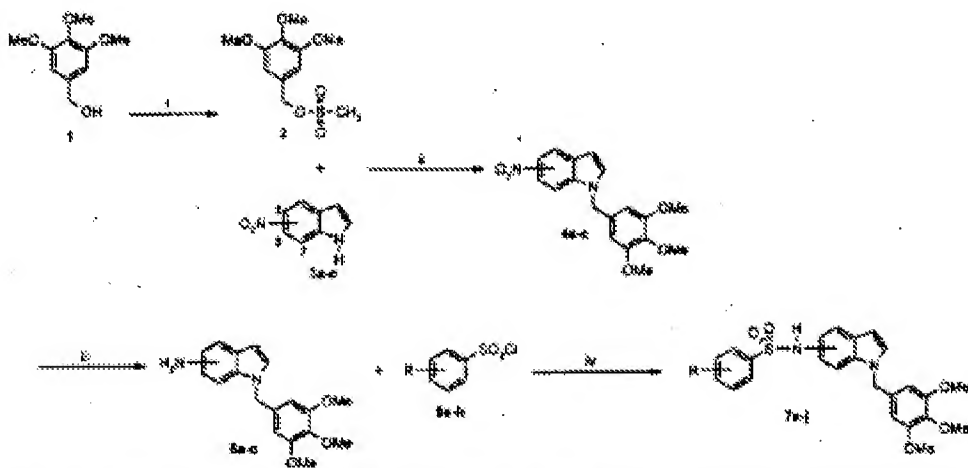
claims 9-14.

34. The '101 application teaches the compound species N-[1-(2-pyrrolidine-1-ylethyl)-1H-indole-6-yl]-naphthalene-1-sulfonamide (claim 8, Example 11) and N-[1-(2-dimethylaminoethyl)-1H-indole-6-yl]-naphthalene-1-sulfonamide (claim 14, Example 3). Accordingly, the only difference between the copending applications is the position of the sulfonamide on the indol ring; namely, position 5 (in the instant application) and position 6 in the '101 application.

35. MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

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36. Furthermore, *Laconde et al* teach compounds having the sulfonamide on position 6 of the indol ring:



Reagents: i. MsCl , Et_3N , CH_2Cl_2 ; ii. K_2CO_3 , Acetone; iii. NH_4Cl , Fe, propan-2-ol; iv. Pyridine, DMF

Compounds	N° of intermediates	Substitution on the indole ring	R	Inhibition (%)*
7a	3a, 4a, 5a	5	H (6a)	0
7b	3a, 4a, 5a	5	2-COOMe (6b)	13.54 \pm 0.7
7c	3a, 4a, 5a	5	4-SO ₂ NH ₂ (6c)	0
7d	3a, 4a, 5a	5	4-Me (6d)	0
7e	3a, 4a, 5a	5	4-Cl (6e)	17.25 \pm 0.8
7f	3a, 4a, 5a	5	4-OMe (6f)	34.50 \pm 1.7
7g	3a, 4a, 5a	5	4-CF ₃ (6g)	0
7h	3a, 4a, 5a	5	2-CF ₃ (6h)	0
7i	3b, 4b, 5b	6	2-COOMe (6b)	15.90 \pm 0.8
7j	3c, 4c, 5c	7	2-COOMe (6b)	45.50 \pm 2.2

(Page 93,

Figure 1). Accordingly, one of ordinary skill in the art would have been motivated to take sulfonamide group or similar variants, and place it at various positions on the indole ring, as they would be expected to have similar properties (for example at position 5, 6, or 7).

37. Claims 18 and 46 of the '101 application are drawn to medicaments containing an excipient. Accordingly, instant claims 18 and 46 are provisionally rejected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

38. **Claims 1-14 and 18 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 18 and 46 of copending Application No. 10/566,403 in view of *Laconde et al* (J Enzyme Inhib Med Chem 18(2):89-94, 2003).** Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

39. As discussed above, the instant application teaches the specie of Formula (Ia) N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 8, Example 17) which reads upon claims 1-8. Copending application teaches N-[1-(2-pyrrolidine-1-yl-ethyl)-1H-indole-7-yl]-naphthalene-1-sulfonamide (claim 8, Example 6).

40. As discussed above, the instant application teaches the specie of Formula (Ib) N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 3). Copending application teaches N-[1-(2-dimethylaminoethyl)-1H-indole-5-yl]-naphthalene-1-sulfonamide (claim 14, Example 1).

41. Claims 18 and 46 of copending application '403 are drawn to compositions comprising the compound and one or more pharmacologically acceptable excipients.

42. For the reasons discussed above claims 1-14 and 18 and 46 are provisionally rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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